



புதுச்சேரி மாநில அரசிதழ்

La Gazette de L'État de Poudouchéry The Gazette of Puducherry

PART - I

சிறப்பு வெளியீடு

EXTRAORDINAIRE

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அதிகாரம் பெற்ற
வெளியீடு

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No. } 15	Poudouchéry	Vendredi	22	Février	2013 (3 Phalgun 1934)
No. }	Puducherry	Friday	22nd	February	2013

GOVERNMENT OF PUDUCHERRY HEALTH SECRETARIAT

No. 3741/CS/Health/ H7/2012.

Puducherry, the 20th February 2013.

NOTIFICATION

The notification in G.S.R. 478 (E), dated 7th August, 1998 of the Department of Health, Ministry of Health and Family Welfare, Government of India, published in the Gazette of India, Part-II, section 3 (i), dated 7th August 1998 is hereby republished for general information of the public.

M. GUNASEKARAN,
Under Secretary to Government (Health).

GOVERNMENT OF INDIA
MINISTRY OF HEALTH AND FAMILY WELFARE
(DEPARTMENT OF HEALTH)

New Delhi, the 7th August 1998.

No. X. 11014/15/94, DM&PFA.- In exercise of the powers conferred by sections 12 and 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government, after consultation with the Drugs Technical Advisory Board, hereby makes the following rules further to amend the Drugs and Cosmetics Rules, 1945, namely:-

1. (1) These rules may be called the Drugs and Cosmetics (Third Amendment) Rules, 1998.

(2) They shall come into force on the date of their publication in the official gazette.

2. In the Drugs and Cosmetic Rules, 1945, for Schedule 'B', the following shall be substituted, namely:-

“SCHEDULE-B
(See rules 7 and 48)

1. Fees for test and assay of drugs requiring use of animals :

	Rupees
Adrenocorticotrophic hormone assay	.. 1,000
Gonadotrophic hormone for LH activity	.. 1,000
FSH activity	.. 1,000
Posterior pituitary extract or its synthetic substitute for oxytocin activity.	.. 400
Vasopressor activity	.. 400
Insulin and insulin in combination for hypoglycaemic activity.	.. 2,000
Hyaluronidase	.. 500
Glucagon	.. 2,000
Heparin for anticoagulant activity	.. 600
Protamine sulphate	.. 300
Depressor or histamine like substance	.. 300
Pyrogen test	.. 500
Antigenicity or foreign protein test	.. 300
Abnormal or undue toxicity or safety test	.. 200
Determination of lethal doses, LD ₁₀ or LD ₅₀ in mice	.. 800
Skin sensitivity/eye irritation	.. 250
Implantation test	.. 2,000

	Rupees
2. Microbiological tests and assays :	
Bioassay of antibiotic	.. 400
Microbiological assay of vitamins	.. 300
Phenol coefficient	.. 300
Preservatives - Microbial challenge test	.. 2,000
Sterility test - Parenteral preparations	.. 100
Surgical dressings	.. 200
Syringes and needles	.. 300
Transfusion and infusion sets of assemblies	.. 400
Other sterile devices.	
3. Identification tests :	
(a) Chemical methods	.. 50
(b) Microscopical	.. 50
(c) IR Spectroscopy	.. 150
(d) UV Spectroscopy	.. 100
(e) Chromotography	
(i) Paper	.. 100
(ii) Thin layer	.. 150
(iii) Column	.. 100
(iv) GLC	.. 250
(v) HPCL	.. 500
(vi) Gel filtration	.. 300
(f) Electrophoresis	
(i) Paper and cellulose acetate	.. 200
(ii) Polyacrylamide gel, starch gel, agar gel	.. 300 each
4. Physical tests :	
(a) Optical rotation, specific gravity, refractive index, weight per ml, fluorescence.	.. 75 each
(b) Viscosity	.. 100
(c) pH, solubility, loss on drying, net content, ash, sulphated ash, etc.	.. 20 each
(d) Absorbancy, wt/unit area (surgical), foreign matter, extractive value, thread count, etc.	.. 30 each
(e) Uniformity of weight	
(i) Tablets	.. 15
(i) Capsules	.. 20
(f) Acid value, iodine value, peroxide value, saponification value, acetyl value.	.. 100 each

	Rupees
(g) Disintegration tests—	
(i) Ordinary tablets	.. 20
(ii) Capsule	.. 30
(iii) Sugar coated tablets	.. 50
(iv) Enteric coated tablets	.. 100
(h) Dissolution test	.. 250
(i) Uniformity of content	.. 500
(j) Wt. per unit area (powder), particle size, count, methoxy value.	.. 200 each
(k) Limit test for impurities	.. 100 each
(l) Related substances	
(i) TLC method—	
(A) Without reference standard	.. 150
(B) With reference standard	.. 250
(ii) Gas Liquid Chromatography—	
(A) Without reference standard	.. 250
(B) With reference standard	.. 350
(iii) High pressure Liquid Chromatography—	
(A) Without reference standards	.. 500
(B) With reference standards	.. 500
(m) Water (Karl Fisher)	.. 200
(5) Assays :	
(a) General chemical methods	.. 100 for each ingredient.
(b) Non-aqueous/Instrumental	.. 200 for each ingredient.
(c) Chromatography—	
(i) TLC	.. 250
(ii) Column	.. 200
(iii) GLC	.. 350
(iv) HPCL	.. 500
(v) Gel filtration	.. 400
(d) Nitrogen determination	.. 200
(e) Medicinal gases	.. 400

	Rupees
(6) Polymorph test :	
(Content of polymorph A in chloramphenicol palmitate) Surgical sutures (Depending on number of test to be carried).	.. 200-500
Other miscellaneous tests	.. 100-500
II. Fees for Sera and Vaccine -	
Sterility test	.. 100
Abnormal toxicity test	.. 400
Specific toxicity test	.. 800
Inactivation test (Rabies)	.. 200
Potency testing of rabies vaccine	.. 2,025
Potency testing of pertussis fraction of DPT vaccine.	.. 2,025
Potency testing of tetanus fraction of DPT/DT/TT vaccine.	.. 2,500
Potency testing of diphtheria fraction of DPT/DT vaccine.	.. 2,700
Testing of antisera for the specific titre	.. 1,000
Potency testing Measles/Mumps/Rubella vaccine	.. 760 each
Testing of Oral Polio Vaccine (OPV)—	
Potency	.. 4,550
Identity	.. 1,000
Stability	.. 800
Potency testing of Japanese encephalitis vaccine	.. 3,900
Potency testing of snake	.. 400
Venom serum	for each venom
Identity testing for vaccines/sera	
Cell culture (Other than OPV)	.. 400
Other than cell culture	.. 100
Estimation of Volume/PH/Total solids/No. of organisms/Physical checking.	.. 50 each
Estimation of total proteins/aluminium content/phenol/formaldehyde/thiomersal/moisture.	.. 200 each
Pyrogen testing	.. 500
Stability test for vaccines other than Oral Polio Vaccine	.. 4,550
III. Cosmetics	.. 400-1,500
(The exact amount of the fee shall be determined by the Director of Laboratory or the Government Analyst, as the case may be).	

		Rupees
IV. Rubber condoms	..	1,000
V. Homoeopathic medicines—		
1. Identification test for raw-material of botanical origin (other than assay of constituents).	..	125
2. Identification test for raw material of chemical origin (other than assay).	..	100
3. Limit test for drugs of chemical origin	..	150
4. Assay of total alkaloids or of drugs of chemical origin.	..	100
5. Identification test for drugs of animal origins or microbiological.	..	100
6. Fees for testing of mother tincture, lower potencies. up to 3x or equivalent.	..	100
7. Determination of biochemic drug through atomic absorbance spectrophotometer.	..	75

Note:

1. For tests not listed in the Schedule, charges will be determined by the Director or the Government Analyst of the laboratory/institute as the case may be.

2. For the tests relating to Ayurvedic, Unani and Siddha medicines, charges will be determined by the Adviser (Indigenous System of Medicine), Director or Government Analyst of the Laboratory/Institute, as the case may be.”.